DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dockets
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[Docket No. 2004N–0337]

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA's and certain Department of Health and Human Services' (HHS) regulatory issues.

Date and Time: The meeting will be held on September 10, 2004, from 8:30 a.m. to 3:30 p.m.

Addresses: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2004 and scroll down to PAC meetings.) Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments.* Select Docket Number 2004N–0337, entitled "Subpart D IRB Referral" and follow the prompts to submit your statement. Written comments should be submitted to Division of Dockets

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Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Received comments may be viewed on the FDA Web site at: *http://www.fda.gov/ohrms/dockets/dockets/04n0337/04n0337.htm* or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Location: Regency Room, DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 17–51), Rockville, MD 20857, 301–827–6687, or by e-mail: *jjohannessen@fda.gov*. Please call the FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001, for up-to-date information on this meeting.

Agenda: On Friday, September 10, 2004, the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss a referral by an Institution Review Board (IRB) of a proposed clinical investigation that involves both an FDA-regulated product and research involving children as subjects that is conducted or supported by HHS. The proposed clinical investigation is entitled "Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder (ADHD): A Functional Magnetic Resonance Study." Because the proposed clinical investigation would be regulated by FDA, and conducted or supported by HHS, both FDA and the Office for Human Research Protections, HHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on ADHD, an overview of the protocol and the referring IRB's

deliberations on the protocol, and a summary of public comments received concerning whether the protocol should proceed, the subcommittee will discuss the proposed protocol and develop a recommendation regarding whether the protocol should proceed. The subcommittee's recommendation will then be presented to the FDA Pediatric Advisory Committee on September 15, 2004; the announcement of the September 15, 2004, meeting can be found elsewhere in this issue of the **Federal Register**.

Also elsewhere in this issue of the **Federal Register** is a document announcing a public comment period concerning whether the proposed clinical investigation should proceed. Information regarding submitting comments during that period is contained in that document.

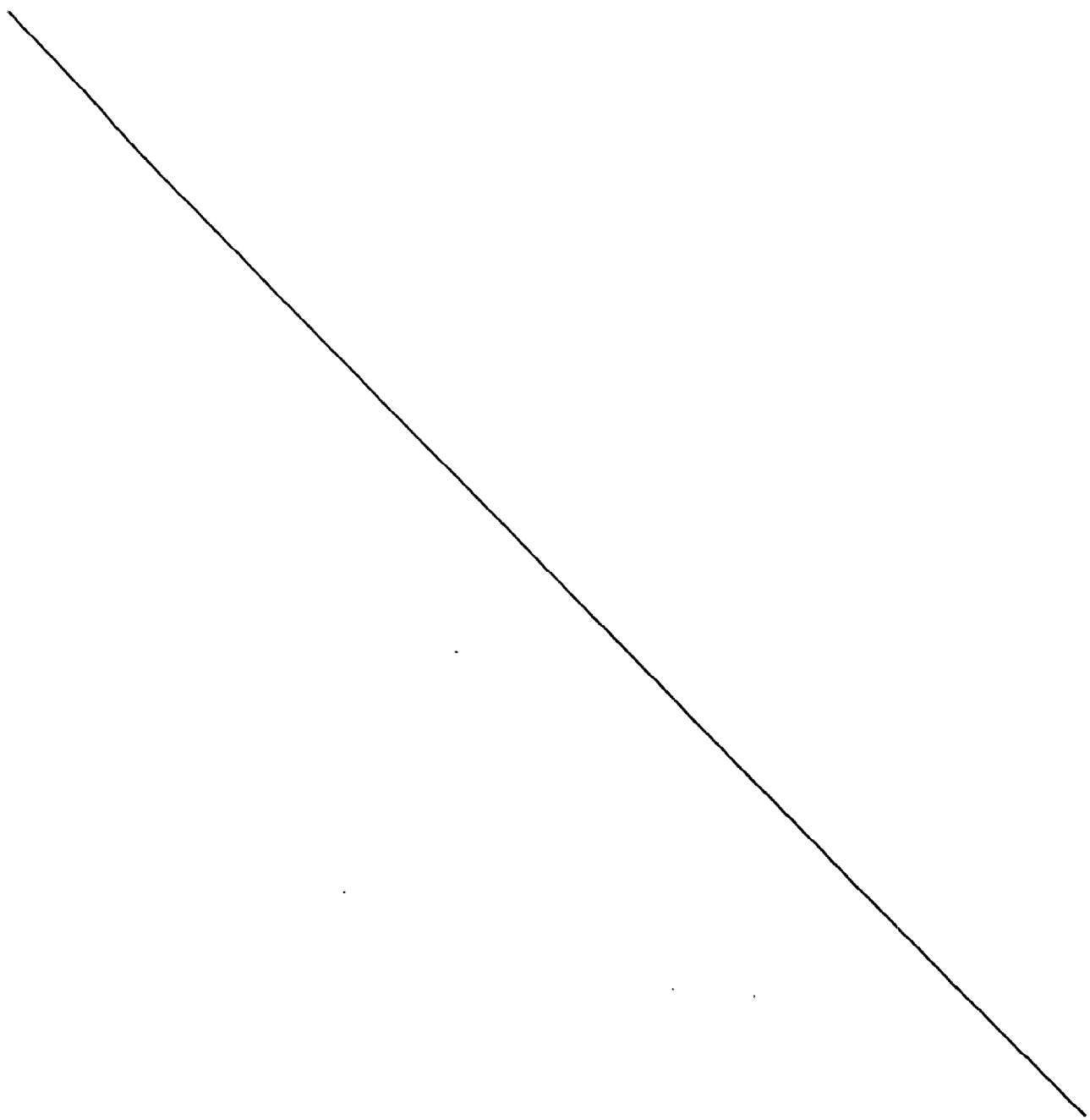
The background materials for the subcommittee meeting will be made publicly available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2004 and scroll down to PAC meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by August 25, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon.

Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by August 25, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Jan Johannessen at least 7 days prior to the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: JUL 29 2004

July 29,2004.

William Hubbard

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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